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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/594,331	06/15/2000	Robert J. Mattila	1894-174	8526	
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	COULTER INC		EXAMII	NER	
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FULLERTON, CA 928343100			,		
			ART UNIT	PAPER NUMBER	
			1743		
			DATE MAILED: 09/11/2002	7	

Please find below and/or attached an Office communication concerning this application or proceeding.

		1/4-7			
	Application No.	Applicant(s)			
Office Action Summers	09/594,331	MATTILA ET AL.			
Office Action Summary	Examin r	Art Unit			
	P. Kathryn Bex	1743			
The MAILING DATE of this communication apperiod for Reply	opears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statu - Any reply received by the Office later than three months after the maili earned patent term adjustment. See 37 CFR 1.704(b).  Status	. 136(a). In no event, however, may a reply be tin ply within the statutory minimum of thirty (30) day d will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).			
1) Responsive to communication(s) filed on 26	August 2002 .				
2a) This action is <b>FINAL</b> . 2b) ⊠ T	his action is non-final.				
Since this application is in condition for allow closed in accordance with the practice unde Disposition of Claims	vance except for formal matters, pr r <i>Ex parte Quayle</i> , 1935 C.D. 11, 4	osecution as to the merits is .53 O.G. 213.			
4)⊠ Claim(s) <u>1-21</u> is/are pending in the application	on.				
4a) Of the above claim(s) 7,8 and 16-21 is/are	e withdrawn from consideration.				
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-6 and 9-15</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/	or election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10) $\boxtimes$ The drawing(s) filed on <u>15 June 2000</u> is/are: a) $\square$ accepted or b) $\boxtimes$ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the E	xaminer.				
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign	gn priority under 35 U.S.C. § 119(a	)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. ☐ Certified copies of the priority documer					
2. Certified copies of the priority documer	its have been received in Application	on No			
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
14) ☐ Acknowledgment is made of a claim for domes					
a)  The translation of the foreign language pr	• • •				
15) Acknowledgment is made of a claim for domes					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)			

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Art Unit: 1743

#### **DETAILED ACTION**

#### Election/Restrictions

1. Applicant's election of Group I in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### **Drawings**

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must *clearly* show every feature of the invention specified in the claims. Therefore, the *vertical* and *horizontal* transport routes, pipette compartment with *spring-loaded v-shaped members*, and *means for positioning on the gripper mechanism*, in claims 1 and 9, 12-13 must be shown or the feature(s) canceled from the claim(s). Although reference number 11 does correspond to the spring-loaded v-blocks, the drawings do not clearly show the invention as specified in the claims. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

## Claim Objections

3. Claim 1 is objected to because of the following informalities: paragraph (e) line 1, recite "a multiplicity of compartment", Examiner believes this should be changed to -- a multiplicity of compartments--. Same deficiency was found in claim 9. Appropriate correction is required.

# Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, paragraph a, line 2, the recitation that an element is "sufficient" to perform a given function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense, see *In re Colianni*, 561 F.2d 220, 222-23, 195 USPQ 150, 152 (CCPA1977). It is not clear as to what Applicant considers "sufficient" thickness of the reagent body.

Same paragraph, the terms "wide" and "narrow" are relative terms which renders the claim indefinite. The terms "wide" and "narrow" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what Applicant considers "wide" middle portions and "narrow" front and rear portions.

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. Claims 1-6, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al (USP 6,293,750 B1) in view of Anami (USP 5,5825,298) and Stylli et al (USP 5,985,214).

Cohen *et al* teach a robotic system for transporting containers and objects within an automated analytical instrument. The analytical instrument 10 has a sample handler module 20 for feeding and storing reagent containers in the instrument 10. Sample handler 20 may include a reagent activator 36 for preparing reagent packages for use by analytical modules. There may also be a module 31 for processing the tubes before analysis, including a predilution apparatus (i.e. pipette) for adding reagents and diluents to and incubating samples. There may also be one or more analytical modules including a clinical analysis module 33, and an immunoassay module represented by box 34. Cohen *et al* teach the robotic transport of reagent containers having an enlongated body with at least one well, with a wide middle and narrow front and rear portions (column 11, lines 3-11, Figs. 12-13). The robot 100 comprises a gantry on a track structure 40 with a two gripping jaws 105. One particular gripping block 560 may be provided on the top of a reagent package, which contains reagents used by instrument 10. Gripping block 560 has a front wall 563 and a back wall (not shown but shaped like front wall 563) which is curved to fit within the contour of fingers 105 and two curved flanges, front flange 561 and rear

flange 562, which may follow the same curvature as the front and back walls. Groove 552 serves to properly align an otherwise misaligned container at the time the container is retrieved. If a reagent package with gripping block 560 or a similar means for gripping the container is not seated at its pick up location completely vertically when robotic arm 100 arrives to pick it up, projections 550, 551 and groove 552 help align the reagent package as fingers 105 close around gripping block 560 by catching flanges 561, 562 of gripping block 560 in groove 552. The top of the flange that is raised too high hits the bottom of projection 551 and is pushed downward while the bottom of the other flange that is too low is pushed upward by the top of lower projection 550. Groove 552 between projections 550, 551 is sized to grasp the top flanges 561, 562 on opposite sides of gripping block 560, while providing some additional space allowance for realignment of the flanges and to prevent flanges 561, 562 from getting stuck in groove (column 12, line 36- column 13, line 18). Additionally, Cohen et al teach a pneumatically operated power assembly (column 10, lines 33-63). Cohen et al do not specifically recite a pipetting nest having a spring-loaded v-shaped members for limiting the movement of the reagent pack during pipetting. Additionally, Cohen et al fail to recite a reagent storage nest having a multiplicity of compartments in both vertical and horizontal rows.

Anami does teach a pipetting nest having spring-loaded v-shaped members 73, 73a for limiting the movement of the container during pipetting (column 9, lines 35-54, Fig. 2). Such a spring-loaded gripping means provides stability while the container is accessed by pipette 50 (column 10, lines 44-45).

Stylli *et al* do teach a 3-dimensional storage and retrieval module for storing and retrieving very large numbers of different reagents in containers (column 6, lines 25-28). The

storage and retrieval module stores the container in hotels 110 with racks 120, having dimensions that allow the container retriever 150 to access a particular container (i.e. vertical and horizontal transfer routes), (column 10, lines 64-66). Such a storage module provides large storage capacity and rapid retrieval of containers, thereby increasing throughput (column 7, line 50-column 12, lines 3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the robotic device of Cohen the pipetting nest having spring-loaded v-shaped members, as taught by Anami, in order to provide stability while the container is accessed by pipette. Further, it would have been obvious to include in the system of Cohen *et al* the storage and retrieval module of Stylli *et al*, in order to provide large storage capacity and the rapid retrieval of containers, thereby increasing throughput.

9. Claims 9-10, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al (USP 6,293,750 B1) in view of Anami (USP 5,5825,298).

Cohen *et al* teach a robotic system for transporting containers and objects within an automated analytical instrument. The analytical instrument 10 has a sample handler module 20 for feeding and storing test tubes of various sizes or reagent containers to the instrument 10. Sample handler 20 may include a reagent activator 36 for preparing reagent packages for use by analytical modules. There may also be a module 31 for processing the tubes before analysis, including a predilution apparatus for adding reagents and diluents to and incubating samples. There may also be one or more analytical modules including a clinical analysis module 33, and an immunoassay module represented by box 34. Cohen *et al* teach the robotic transport of reagent containers having an elongated body with at least one well, with a wide middle and

narrow front and rear portion (column 11, lines 3-11, Figs. 12-13). The robot 100 comprises a gantry on a track structure 40 with a two gripping jaws 105. One particular gripping block 560 may be provided on the top of a reagent package, which contains reagents used by instrument 10. Gripping block 560 has a front wall 563 and a back wall (not shown but shaped like front wall 563) which is curved to fit within the contour of fingers 105 and two curved flanges, front flange 561 and rear flange 562, which may follow the same curvature as the front and back walls. Groove 552 serves to properly align an otherwise misaligned container at the time the container is retrieved. If a reagent package with gripping block 560 or a similar means for gripping the container is not seated at its pick up location completely vertically when robotic arm 100 arrives to pick it up, projections 550, 551 and groove 552 help align the reagent package as fingers 105 close around gripping block 560 by catching flanges 561, 562 of gripping block 560 in groove 552. The top of the flange that is raised too high hits the bottom of projection 551 and is pushed downward while the bottom of the other flange that is too low is pushed upward by the top of lower projection 550. Groove 552 between projections 550, 551 is sized to grasp the top flanges 561, 562 on opposite sides of gripping block 560, while providing some additional space allowance for realignment of the flanges and to prevent flanges 561, 562 from getting stuck in groove (column 12, line 36- column 13, line 18). Additionally, Cohen et al. teach in an alternative embodiment pneumatically operated power assembly (column 10, lines 33-63). Cohen et al do not specifically recite a pipetting nest having a spring-loaded v-shaped members for limiting the movement of the reagent pack during pipetting. Anami does teach a pipetting nest having spring-loaded v-shaped members 73, 73a for limiting the movement of the

container during pipetting (column 9, lines 35-54, Fig. 2). Such a spring-loaded gripping means provides stability while the container is accessed by pipette 50 (column 10, lines44-45).

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Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the robotic device of Cohen the pipetting nest having spring-loaded v-shaped members, in order to provide stability while the container is accessed by pipette.

#### Conclusion

- 10. No claims allowed.
- 11. The prior art made of record and not relied upon which is considered pertinent to applicant's disclose are Bevirt et al, Kedar et al, Miller et al, Torchia et al, Ootani et al, and Ashiara et al. They are cited of interest in that they show various automated analyzers with robotic transport means.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex P. Kathryn Bex

Patent Examiner

AU 1743

September 9, 2002

Supervisory Patent Examiner Technology Center 1700